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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte NICOLAS M. VALIANTE

Appeal 2010-009847
Application 10/762,873
Technology Center 1600

Before ERIC GRIMES, MELANIE L. McCOLLUM, and STEPHEN WALSH, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an immunogenic composition, which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 12-17 and 19 are on appeal. Claim 12 is the only independent claim and reads as follows:

12. An immunogenic pharmaceutical composition comprising an antigen and a tryptanthrin compound adjuvant in an amount effective to

provide an enhanced immune response to the antigen relative to the response provided without the tryptanthrin compound adjuvant.

"Tryptanthrin (indolo-[2,1-b]quinazolin-6,12-dione) is a material that is produced naturally in some plant species, and has been produced synthetically . . . . Tryptanthrin and some of its analogs have been shown to exhibit some antimicrobial activity." (Spec. 2, ¶ 9.)

The Examiner has rejected claims 12-17 and 19 under 35 U.S.C. § 103(a) as obvious based on Baker[1] and Colston[2] (Answer 3). The Examiner finds that Baker discloses an antimicrobial composition comprising a tryptanthrin compound that can be combined with other agents used to treat pathogenic mycobacterial infections (*id.* at 3-4) but does not teach combining the tryptanthrin compound with an antigen (*id.* at 5). The Examiner finds that Colston discloses recA mutant mycobacteria that can be used as an antigen delivery system in treating diseases, such as pathogenic infection (*id.* at 5-6).

The Examiner concludes that it would have been obvious to combine Baker's tryptanthrin compound with a composition comprising antigens associated with tetanus or diphtheria because Baker teaches that its tryptanthrin compound can be combined with another agent for treating pathogenic mycobacterial infections and Colston teaches that its mutant mycobacteria can be used as an antigen delivery system for delivering antigens such as tetanus toxin and diphtheria toxin (*id.* at 6-7).

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[1] Baker et al., US 5,441,955, Aug. 15, 1995
[2] Colston et al., US 7,122,195 B2, Oct. 17, 2006

Appellant argues that Baker and Colston are fundamentally incompatible because Baker discloses that its tryptanthrin compound kills mycobacteria, while Colston's vaccine compositions require live mycobacteria to be effective (Appeal Br. 7-8, Reply Br. 3).

We agree with Appellant that the Examiner has not shown that it would have been obvious to combine Baker's tryptanthrin compound with Colston's antigen-expressing mycobacteria. Baker discloses tryptanthrin compounds (Baker, col. 2, l. 61 to col. 3, l. 2; col. 20, ll. 22-33) that inhibit the growth of pathogenic mycobacteria and can be used to treat mycobacterial infections (*id.* at col. 3, ll. 16-22; col. 46, l. 57 to col. 48, l. 40).

Colston discloses a "cell of a mycobacterium which is a member of the *M. tuberculosis* complex and which has an inactivated recA function" (Colston, col. 3, ll. 40-42). Colston discloses that such a cell "persists in a host immunized therewith" and "is able to persist in tissue without causing progressive infection" (*id.* at col. 3, ll. 49-53). Colston discloses that an "*M. tuberculosis* complex cell of the present invention may further comprise a gene encoding a polypeptide which is a non-mycobacterial or foreign antigen. Expression of such an antigen . . . allows the generation of an immune response in a vaccinated individual." (*Id.* at col. 4, ll. 51-56.) Colston discloses that its cells "may therefore be used as an antigen delivery system in the treatment of any disease, such as a pathogenic infection, which is ameliorated by an immune response against a particular antigen" (*id.* at col. 4, ll. 57-60).

Thus, as Appellant has pointed out, Colston discloses that its mycobacteria function as an antigen-delivery system by persisting in a

vaccinated individual and expressing an antigen to generate an immune response, while Baker discloses that its tryptanthrin derivatives can be used to treat mycobacterial infections by inhibiting the growth of mycobacteria. We agree with Appellant that it would not have been obvious to combine the disclosures of Baker and Colston because Baker's tryptanthrin compound would be expected to kill or at least inhibit the growth of Colston's mycobacterial antigen-delivery system. We also agree with Appellant (Reply Br. 2-3) that the Examiner's argument to the contrary – that Appellant is "arguing against their own claimed invention" (Answer 7) – is inapplicable because the claims do not require the antigen to be expressed by a live mycobacterial cell.

SUMMARY

We reverse the rejection of claims 12-17 and 19 as obvious based on Baker and Colston.

REVERSED

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